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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/218,660	12/22/1998	EVAN C. UNGER	IMARX1100-3	2775
28213 DLA PIPER U	7590 08/27/2007 JS LLP		EXAMINER	
4365 EXECUTIVE DRIVE			SOROUSH, LAYLA	
SUITE 1100 SAN DIEGO,	CA 92121-2133	92121-2133		PAPER NUMBER
,			1617	
			MAIL DATE	DELIVERY MODE
			08/27/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

****	10.00	Application No.	Applicant(s)
Office Action Summary		09/218,660	UNGER ET AL.
		Examiner	Art Unit
		Layla Soroush	1617
Period fo	The MAILING DATE of this communication app or Reply	ears on the cover sheet with	the correspondence address
A SH WHIC - Exte after - If NC - Failu Any	ORTENED STATUTORY PERIOD FOR REPLY CHEVER IS LONGER, FROM THE MAILING DANS IN THE MAIL	ATE OF THIS COMMUNIC, 16(a). In no event, however, may a repril apply and will expire SIX (6) MONTH cause the application to become ABA	ATION.  Sly be timely filed  HS from the mailing date of this communication.  NDONED (35 U.S.C. & 133)
Status	· · · · · · · · · · · · · · · · · · ·		
2a)	Responsive to communication(s) filed on 19 Ma This action is FINAL. 2b) This Since this application is in condition for allowant closed in accordance with the practice under E.	action is non-final. ice except for formal matte	
Dispositi	ion of Claims		
5) 6) 7)	Claim(s) <u>See Continuation Sheet</u> is/are pending 4a) Of the above claim(s) is/are withdraw Claim(s) is/are allowed. Claim(s) is/are rejected. Claim(s) is/are objected to. Claim(s) <u>See Continuation Sheet</u> are subject to	n from consideration.	requirement.
Applicati	on Papers		
10) 🗌	The specification is objected to by the Examiner The drawing(s) filed on is/are: a) access applicant may not request that any objection to the conference of the con	epted or b) objected to by frawing(s) be held in abeyance on is required if the drawing(s)	e. See 37 CFR 1.85(a). ) is objected to. See 37 CFR 1.121(d).
Priority u	ınder 35 U.S.C. § 119		
a)[	Acknowledgment is made of a claim for foreign All b) Some * c) None of:  1. Certified copies of the priority documents 2. Certified copies of the priority documents 3. Copies of the certified copies of the priori application from the International Bureau see the attached detailed Office action for a list of	have been received. have been received in App ty documents have been re (PCT Rule 17.2(a)).	olication No eceived in this National Stage
2) 🔲 Notice 3) 🔲 Inform	t(s) e of References Cited (PTO-892) e of Draftsperson's Patent Drawing Review (PTO-948) nation Disclosure Statement(s) (PTO/SB/08) r No(s)/Mail Date	Paper No(s)/I	mmary (PTO-413) Mail Date rmal Patent Application

Continuation of Disposition of Claims: Claims pending in the application are 100,102,127,194-200,203,210-213,217-228,294-300,303,310-329,331-337,347-356 and 412.

Continuation of Disposition of Claims: Claims subject to restriction and/or election requirement are 100,102,127,194-200,203,210-213,217-228,294-300,303,310-329,331-337,347-356 and 412.

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## **DETAILED ACTION**

The response filed March 19, 2007 presents remarks and arguments submitted to the office action mailed December 19, 2006 is acknowledged.

The arguments that "the Applicants have demonstrated that every limitation of the claims of this continuation-in-part application is disclosed in the parent application in such a way as to satisfy the requirements of 35 U.S.C. § 112" has been considered and is persuasive. Upon further consideration of the claims the following restriction is required.

## Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 100, 102, 194-200, 203, 210, 211-213, 217-228, and 412 are drawn to a formulation for therapeutic or diagnostic use comprising targeted gas-filled vesicles which comprise one or more membranes, wherein each of said membrane is in solid state, each of said membranes defining an internal void that contains a substantially insoluble substance, the substance being in a gaseous form at ambient conditions, the substance selected from the group consisting of perfluorocarbons and sulfi- hexafluoride, said solid state membrane comprising a phospholipid, and being free of disulfide linkages, and further comprising a lipid covalently conjugated to a targeting ligand via a linking group, wherein said linking group is a hydrophilic polymer selected from the group consisting of polyethylene glycol (PEG), polypropylene glycol,

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polyvinylalcohol, polyvinylpyrrolidone, and copolymers thereof, and wherein said targeting ligand is selected from the group consisting of proteins, peptides, saccharides, steroids, steroid analogs, bioactive agents and genetic material., classified in class 424, subclass 001.210.

II. Claims 127, 294-300, 303, 310-329, 331-337, and 347-356 are drawn to a formulation for therapeutic or diagnostic use comprising formulation for therapeutic or diagnostic use comprising substance, the substance being in a gaseous form at ambient conditions, the substance selected from the group consisting of perfluorocarbons and sulfur hexafluoride, said solid state membrane comprising a phospholipid, and being free of disulfide linkages, and further comprising a lipid covalently conjugated to a targeting ligand via a linking group, wherein said linking group is a hydrophilic polymer selected from the group consisting of polyethylene glycol (PEG), polypropylene glycol, polyvinylalcohol, polyvinylpyrrolidone, and copolymers thereof, and wherein said targeting ligand is selected from the group consisting of proteins, peptides, saccharides, steroids, steroid analogs, bioactive agents and genetic material, classified in class 424, subclass 001.210.

Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of

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using that product. See MPEP § 806.05(h). In the instant case the product claimed can be used as a contrast agents in ultrasound echography.

Because these inventions are distinct for the reasons given above and the search required for Group I is not required for Group II, restriction for examination purposes as indicated is proper. The searches in non-patent literature databases are extensive and do not overlap thus presenting a search burden to be searched together. Thus, Groups I and II have been appropriately restricted on the basis of being independent or distinct and presenting a search burden on the Examiner if they were to be searched together.

The examiner has required restriction between product and process claims.

Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder.

All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product

claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. Failure to do so may result in a loss of the right to rejoinder. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

## Election

A telephone call to the attorney is not required where: 1) the restriction requirement is complex, 2) the application is being prosecuted pro se, or 3) the examiner knows from past experience that a telephone election will not be made (MPEP 812.01). Since the restriction election is considered complex, a call to the attorney for a telephone election was not made.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

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## Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Layla Soroush whose telephone number is (571)272-5008. The examiner can normally be reached on Monday through Friday from 8:30 a.m. to 5:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SREENI PADMANABHAN SUPERVISORY PATENT EXAMINER